

Will anything really change? Views from a representative of the health authorities

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Beyond any doubt, the Sudbø case has had multiple effects. It has contributed both to an increased awareness and debate, to further development of systems for handling fraud, to a new law, and it has stated clearly the consequences and the seriousness of fraud in medical research.

Awareness about uncertainties of scientific results

Results from research have to be handled with caution. This has become especially clear after the extreme case of scientific misconduct by Jon Sudbø. As part of the Norwegian Health Authorities, the Norwegian Directorate for Health and Social Affairs is in its work highly dependent on scientifically based knowledge. The Directorate commissions such knowledge to a substantial extent. The handling of the results from investigation and research has hitherto not necessarily been subject to enough critical consideration. Not only conscious fraud, but also more or less unconscious mistakes, misinterpretations, or faults can occur throughout the whole process of commissioning, planning, and conducting a study to the reporting and implementation of the results. Attention and better understanding of the uncertainties connected to all scientific results are beneficial effects.

Critical approach to authorities' own administrative work

Health authorities, again speaking on behalf of the Directorate, have become more aware of their own contribution to quality assurance of scientifically based knowledge. Both commissioning, assessment and implementation of scientific results in practice or administration has to be subject to critical thinking. The directorate has started establishing better routines aimed at achieving better quality.

In addition, the case has also contributed to a more critical approach to the directorate's other administrative work and a better understanding of the fact that this kind of critical approach is necessary for achieving better quality.

Responsibility for reliability of research and the results

Authorities abruptly have become aware of the fact that control mechanisms for securing the quality of research and the reliability of results have not been sufficient. Those who really go for cheating might not be hindered in any case, but still the Sudbø case uncovered weaknesses in the system for handling fraud in science. The Investigation Commission recommended in its report "that institutions take more responsibility for raising awareness and instructing their researchers about the rules that apply, and that they engage in at least a minimum of verification and control, taking appropriate account of academic freedom."

Simultaneously, the long discussed question of responsibility has found an answer: There is no longer any doubt about institutions being responsible. This is true both for prevention of fraud, for education of scientists, and for the handling of misconduct in science.

Pushing for better routines in research institutions

The initiative for developing better routines is left to the research institutions, although authorities are critically following the progress. There is no doubt that the reliability of science in general and of the responsible institution in particular is weakened after the Sudbø case, and that the handling must be observed with great attention.

The National Committee for Research Ethics in Norway is investigating what measures now are taken by research institutions. They have developed a check list on research ethics to be used by scientists. Guidelines, contracts, and other tools are made more easily accessible. A new contract for commissioned research is developed by the Ministry for Knowledge.

Legal instruments

Some years before the Sudbø case, a new Act legalizing The National Committees for Research Ethics in Norway and an Investigating Committee for Ethics in Research was proposed (Ot.prp. nr.58 (2005-06)). This work was quickly resumed and the law was passed this year.

Before the Sudbø case became public, the Official Norwegian Report “Good Research, Better Health” by the Nylenna Committee (NOU 2005:1) had proposed a new Act related to medical and health research, aiming at promoting and improving research and simplifying the approval. By making the system more transparent and by establishing defined rights for researchers and requests to research organisations, the intention was to promote good, ethically justifiable medical and health research. The Ministry’s process connected to this new Act is in progress and the Sudbø case has emphasized its importance.

Factors influencing ethical behaviour in research

Scientists are under pressure and this may influence their behaviour. As an example, the funding of the scientists’ own careers and also their host institutions’ economy, is today dependent on the publication of articles based on results from research and on the prestige of journals. This situation must be considered as a strong incentive for short cuts, pushing towards more and quicker publication and co-authorships.

The Sudbø case has emphasized the great responsibility for quality assurance lying on the coauthors and the obstacles connected to this system. Research today is to a great extent based on team work, both across institutions and nations. The recent debate has drawn attention to the fact that often the only way to compensate for contributions in a scientific project is to offer a co-authorship, although the contribution might not have been sufficient according to the Vancouver guidelines.

Authorities ought to consider how to implement incentives and provide working conditions for scientists such that ethical behaviour is promoted. They need to ensure that this is not counteracted by the financing systems.

Serious consequences of fraud

Health authorities, represented by the Norwegian Board of Health, now have stated how seriously they consider fraud in medical research. Sudbø has not only lost his professional honour, but also his working place, his Ph.D. and the right to practice as a doctor and dentist for the rest of his life. The sentence is putting an end to his professional career, is covered by great public interest both nationwide and internationally, and seems irreversible.

The sentence over Sudbø seems unusually tough, compared to crimes and mistakes in other parts of society. This underlines the great responsibility lying on the shoulders of scientists and health personal and the ab-

solute need for reliability. Implementation of false results from research can endanger patients. Implementation of false results into politics can lead to wrong decisions and waste of substantial resources.

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